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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,864	04/12/2002	Renato Pedrazzi	02508.0095	3251

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Washington, DC 20005-3315

EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/980,864	Applicant(s) PEDRAZZI, RENATO	
	Examiner John Kim	Art Unit 1723	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24, 33, 34, 38 and 39 is/are rejected.
- 7) ☒ Claim(s) 25-32, 35-37 and 40-47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other:  |

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1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. Claims 29, 31, 35-36 and 44 are objected to because of the following informalities:

Claims 29, 35 and 44 shows  $Q_b$  in these claims, but  $Q_b$  is not described in these claims.

Recitation of "one of the" in on line 1 of the claim 36 should be removed to show its sole dependence on claim 34. Terms  $P_{bo}$  and  $P_{bi}$  in claims 31, 36 and 46 should be reversed to show corresponding blood pressure values at the inlet and at the outlet of the blood compartment of filter. Appropriate correction is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 23-24, 33-34 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 23-24, 33-34 and 38-39 are indefinite for failing to particularly point out whether at least one characteristic value is limited to FF (filtration factor), TMPave (mean transmembrane pressure) and Kuf (actual permeability). Furthermore, such terms FF, TMPave and Kuf should be described in the claims in words. For examination purpose, one characteristic value is limited to one of FF, TMPave and Kuf.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,762,805 (hereinafter referred to as Truitt et al) in view of English translated copy of WO 98/50091 A1 (hereinafter referred to as WO translation). Truitt et al teach a device for extracorporeal purification of blood comprising a blood filtration unit (40) having a primary chamber (44) i.e. blood compartment and a secondary chamber (46) i.e. dialysis liquid compartment separated by a semi-permeable membrane (42), a primary circuit i.e. extracorporeal blood circuit having a blood extraction conduit (34) i.e. arterial pipe and a blood return conduit (35) i.e. venous pipe connected to a primary chamber (44), a secondary circuit i.e. dialysis liquid circuit having a supply conduit and a evacuation conduit (82) connected to the secondary chamber, ultrafiltrate pump (84) to cause ultrafiltrate to flow in the evacuation conduit (82), a source of substitution solution (68) i.e. infusion liquid, a connecting conduit (70) between the source of substitution solution (68) and the blood return conduit (35), a pump (66) to cause the substitution solution to flow in a connecting conduit (70) downstream of the filter (40) i.e. post dilution control means, pressure sensors (51, 53, 54, 84) for measuring transfilter pressure or transmembrane pressure i.e. a parameter influenced by the resistance of the filtration unit (40) to the flow of liquid (see figures 1-2; col. 3, line 59 – col. 6, line 20), a computation unit comprising a control unit (102) connected to a monitor unit (104) for monitoring pressure sensors (51, 53, 54, 84) and for controlling a pump (66) for controlling the substitution solution to flow in a

connecting conduit (70) (see figures 3a-3b; col. 6, line 43 – col. 11, line 40) wherein the control processor (122) in the control unit (102) receives signals from the monitor processor (140) in the monitor unit (104) and transmits signals to a motor controller (128) to halt a pump (66) whenever pressure sensors (51, 53, 54, 84) signal an abnormal pressure value from predetermined stored pressure value and allows operator to adjust the treatment steps to continue the treatment (see col. 17, line 31 – col. 18, line 27; col. 16, lines 10-40). Truitt et al further teaches that the connecting conduit (70) can be connected to a primary circuit (30) upstream of the primary chamber (44) of the filtration unit (40) wherein a pump (66) causes the substitution fluid to flow upstream of the filtration unit (40) in the blood extraction conduit i.e. pre-dilution control means (see col. 5, lines 31-45). Claim 22 essentially differ from the apparatus of Truitt et al in reciting control means for controlling the flow varying means so that the flow of the infusion liquid in the pre-dilution pipe and the post-dilution pipe matches a determined sequence. WO translation teaches a blood purification device comprising electronic control means (9-14) which based on measurements from pressure gauges 2'-3'-4' and balances 5-6-7 to steer flows applied by pumps 1-4 including a pump (2) for replacement fluid i.e. infusion liquid wherein replacement fluid is brought by means of pump (2) from receptacle (15) with a flow divider regulating the proportion between the flow of replacement fluid injected into the blood circulation upstream from the filtration means (8) and the flow of replacement fluid injected into the blood circulation downstream from the filtration means (8) (see figure; page 11, 2<sup>nd</sup>-4<sup>th</sup> paragraphs). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Truitt et al to incorporate control means for controlling the flow varying means for the flow of the infusion liquid in the pre-dilution pipe and the post-dilution pipe to improve

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control of infusion liquid flow in the pre-dilution and post dilution pipe as suggested by WO translation.

7. Claims 25-32, 35-37 and 40-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 33-34 and 38 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

9. Claims 23-24 and 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,471,872 teaches blood purification apparatus comprising hematocrit sensor and related control.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

A handwritten signature in black ink, appearing to read "John Kim", is positioned above the printed name.

**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
September 4, 2003